In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 05-605V

Filed: August 28, 2009

NOT TO BE PUBLISHED

PAMELA DOYLE and JOSEPH DOYLE on behalf of KATELYN DOYLE,	*	
Petitioners,	*	Entitlement; MMR; ITP; Althen Prong Three; Appropriate Temporal Relationship; Acute Versus Chronic ITP; Insidious Onset of Chronic ITP.
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Peter H. Meyers, National Law Center, Washington, D.C., for petitioners

Alexis B. Babcock, U.S. Department of Justice, Washington, D.C., for respondent

DECISION[1]

GOLKIEWICZ, Chief Special Master.

PROCEDURAL BACKGROUND

On June 5, 2007, petitioners Pamela Doyle and Joseph Doyle filed a petition on behalf of

[1] Because this decision contains a reasoned explanation for the undersigned's action in this case, The undersigned intends to post this decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire decision will be available to the public. Id.

their daughter, Katelyn Doyle, pursuant to the National Vaccine Injury Compensation Program[2] ("the Act" or "the Program") alleging that Katelyn suffered an injury of idiopathic thrombocytopenic purpura (hereinafter "ITP")[3] that was caused-in-fact by the MMR vaccination received on October 15, 2002. Petition (hereinafter Pet.) at 1, filed June 7, 2005. Respondent filed Respondent's Rule 4(c) Report on January 19, 2006, stating that petitioners have "not provided any substantive evidence that supports an argument for a Table injury or actual causation," and requested that the petition be denied and the case dismissed. Respondent's Rule 4(c) Report (hereinafter R.4 Report), filed Jan. 19, 2006. A fact Hearing was held on April 28, 2006. Subsequently, the undersigned issued an Order and Ruling on Factual Issues, finding that "the bruising seen on Katelyn was nothing out of the ordinary for her until sometime after the April 2003 visit and prior to the July visit." Order and Ruling on Factual Issues (hereinafter Fact Ruling) at 2, filed Dec. 22, 2006. The undersigned further stated that there was no "persuasive information in this record to distinguish the bruising **before and after** the vaccination given on October 15, 2002." Id. at 2-3 (emphasis added). Following the issuance of the undersigned's Fact Ruling the parties pursued filing medical expert reports. Petitioners filed an expert report from Dr. S. Gerald Sandler on September 27, 2007. Petitioners' Exhibit (hereinafter P Ex) 18, filed Sept. 27, 2007. Respondent filed an expert report from Dr. James Nachman on December 28, 2007. Respondent's Expert Report, filed Dec. 28, 2007.[4] An expert Hearing was conducted in Washington, D.C., on June 30, 2008. After the Hearing petitioners filed a supplemental expert report from Dr. Sandler on July 24, 2008. P Ex 37. Respondent filed a supplemental expert report of Dr. Nachman on August 18, 2008. R Ex C. The parties filed simultaneous post-Hearing briefs on February 9, 2009. P Post-Hearing Brief, filed Feb. 9, 2009; R Post-Hearing Brief, filed Feb. 9, 2009. Likewise, on February 23, 2009, the parties filed simultaneous responses to the post-Hearing briefs. P Response to Respondent's Post-Hearing Brief (hereinafter P Response), filed Feb. 23, 2009; R Response to Petitioners' Post-Hearing Brief (hereinafter R Response), filed Feb. 23, 2009. The case is now ripe for resolution.

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[2] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. §§ 300aa-10 et seq. (2006) ("Vaccine Act" or the "Act"). Hereinafter, individual section references will be to 42 U.S.C.A. § 300aa of the Vaccine Act.

[3] Thrombocytopenia means "decrease in number of platelets, such as in thrombocytopenic purpura..." Dorland's Illustrated Medical Dictionary (30th ed. 2003) 1906. Petitioners' expert, Dr. Sandler, see page 5, infra, defined ITP as a "disease whereby platelets are destroyed by their own defense mechanism, particularly something known as antibodies." Tr. at 18.

[4] Respondent filed two exhibits labeled as Exhibit A, the first exhibit filed as Exhibit A was an Affidavit of Donna Jackson, R.N., F.N.P., filed on June 23, 2006. Subsequently, respondent filed respondent's expert report from Dr. Nachman on Dec. 28, 2007 as Exhibit A. For clarity the undersigned will refer to the first Exhibit A as the "Affidavit of Donna Jackson" and the second Exhibit A as "Respondent's Expert Report."

FACTUAL BACKGROUND

An extensive discussion of the facts is included in the Fact Ruling. Thus, the undersigned limits the factual discussion in this decision to facts pertinent to the instant decision. Katelyn Doyle was born via cesarean section on October 10, 2001. P Ex 6 at 32. Her APGAR scores were nine and nine at one and five minutes, respectively. Id. at 33. She was seen regularly and treated for normal childhood ailments. See generally P Ex 3. Katelyn was seen on October 15, 2002 at Wake County Human Services (WCHS) for a twelve month visit. P Ex 3 at 14. The office notes from this visit indicate that Katelyn was "[d]oing well," that there were "[n]o ques[tions] or concerns" and she was okay for immunization. Id. (her mother did note an allergic reaction to fruit). Katelyn received an MMR vaccination and varicella vaccination at this office visit. P Ex 2 at 4. Katelyn was next seen at WCHS on April 15, 2003. P Ex 3 at 16. During this office visit Katelyn was deemed a well-child and was thoroughly examined by a nurse named Donna Jackson. P Ex 3 at 16; see also Affidavit of Donna Jackson. In her affidavit Nurse Jackson detailed in the normal course of practice her method of examining a child. Affidavit of Donna Jackson. Nurse Jackson specifically stated that she would physically exam the child to check the skin for "lesions, abrasions, rashes, or any other abnormalities." Id. at 2. She also indicated that if a child's legs or arms were covered with clothing she would have the child undress "to enable a complete observation." Id. In this case, Nurse Jackson stated that while she had no independent recollection of Katelyn's visit on April 15, 2003, after reviewing her notes she maintained that had she observed any abnormalities in Katelyn she would have written them down. Id. at 3. Her observations would then be coupled with reviewing a parent completed questionnaire with the parents to see if the parents had any specific concerns. Id. Katelyn's mother filled out a questionnaire on April 15, 2003 where she answered "no" to the questions of whether her child was sick recently and if she had any concerns about her child's health. P Ex 3 at 17; see also Fact Ruling at 2. No symptoms of ITP were documented at Katelyn's April 15, 2003 office visit. P Ex 3 at 16. The undersigned found in the Fact Ruling that the "bruising seen on Katelyn was nothing out of the ordinary for her until sometime after the April 2003 visit and prior to the July visit." Fact Ruling at 2. The July visit referenced was the July 8, 2003 office visit where Katelyn's mother reported that Katelyn has "always bruised easily" and the number of bruises has increased since she started walking. P Ex 3 at 18. Her mother was particularly concerned about a tender "purplish 'knot'" on Katelyn's side. Id. Katelyn is described by her mother as "very active" and "very accident prone." Id. On July 9, 2003, Katelyn had blood work performed which revealed a platelet count of 19,000.[5] P Ex 5 at 3; see P Ex 4 at 18. She was admitted to the University of North Carolina Hospital (UNC hospital) with a chief complaint of "[t]hrombocytopenia." P Ex 4 at 45 (discharge summary from Dr. Brent Weston, M.D.). Under Assessment and Plan Dr. Weston notes that "[t]his is a 20-month-old female with **new-found** thrombocytopenia and increased bruising." Id. at 47 (emphasis added). Under the History section it states that Katelyn had "increased severity of bruising over the last several months."

[5] Under the Act's Qualifications and Aids to Interpretation (QAI), thrombocytopenic purpura is defined by a "serum platelet count less than 50,000/mm super3." 42 C.F. R. § 100.3 (b)(8). Petitioners are not alleging a Table injury in this case. See Tr. at 7-8.

Id. at 45. Dr. Weston diagnosed Katelyn with idiopathic thrombocytopenic purpura, chronic versus acute. Id. at 47. Katelyn received treatment for her ITP over the next year and was diagnosed with chronic ITP at her July 7, 2004 office visit with Dr. Julie Blatt, M.D. P Ex 4 at 76-77. Currently, Katelyn's ITP is in "remission." Transcript of Hearing held June 30, 2008 (hereinafter "Tr.") at 26-27.

Issue

The accepted temporal relationship between the MMR vaccine and ITP, as supported by the medical literature, is onset within six weeks of vaccination. See infra pp. 7-8. The medical records and the facts as determined by the undersigned do not support the presence of symptoms of onset of Katelyn's ITP within six weeks following her immunizations. See Fact Ruling. Petitioners concede that they cannot establish a Table case and are not claiming that the vaccines aggravated a pre-existing condition. Tr. at 7-8. Petitioners contend, however, through their expert, that Katelyn's ITP was caused in-fact by her immunizations. Recognizing that the precise onset date of Katelyn's ITP is "very difficult" if not "impossible" to determine, tr. at 9, petitioners nevertheless contend the Katelyn's ITP is "very rare and unusual, id., one of less than 5% of ITP cases in children, that presents with an "insidious onset." Id. Petitioners propose that Katelyn's ITP was percolating below the surface absent evidence of bruising. Tr. at 39. Petitioners rely on an insidious onset to explain the lack of documented symptoms of ITP within the medically accepted time frame. Respondent maintains that there is no basis for petitioners' claim of an insidious onset and, therefore, there is no appropriate temporal relationship between vaccine and injury in this case. Thus, the main issue centers on petitioners' claim that Katelyn's ITP is a rare form that presented in an insidious manner and whether petitioners have established by the preponderance of the evidence a proximate temporal relationship between the vaccine and Katelyn's injury.

Legal Standard

Causation in Vaccine Act cases can be established in one of two ways: either through the statutorily prescribed presumption of causation or by proving causation-in-fact. Petitioners must prove one or the other in order to recover under the Act. According to §13(a)(1)(A), claimants must prove their case by a preponderance of the evidence.[6]

For presumptive causation claims, the Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable

[6] A preponderance of the evidence standard requires a trier of fact to "believe that the existence of a fact is more probable than its nonexistence before the [special master] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." In re Winship, 397 U.S. 358, 372-73 (1970) (Harlan, J. concurring) (quoting F. James, CIVIL PROCEDURE, 250-51 (1965)). Mere conjecture or speculation will not establish a probability. Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984).

presumption that the vaccine caused the injury or condition. 42 U.S.C. §300aa-14(a). As stated previously, petitioners concede that they cannot establish a Table injury. See Tr. at 7. Thus, petitioners must prove that the vaccinations in-fact caused Katelyn's injuries, a so-called "off-Table" case.

In Althen v. Sec'y of Dept. of Health & Human Servs., 418 F.3d 1274,1278 (Fed. Cir. 2005), the Court of Appeals for the Federal Circuit reiterated that petitioners' burden is to produce "preponderant evidence" demonstrating: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and injury." Id.; see also Andreu ex rel. Andreu v. Sec'y of HHS, 569 F.3d 1367, 2009 WL 1688231 (Fed. Cir. 2009).[7] The Federal Circuit in Althen stated further that "requiring that the claimant provide proof of medical plausibility, a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes – is merely a recitation of this court's well established precedent." Althen at 1281. The Federal Circuit concluded that to support petitioners theory of causation, there is no requirement in the Vaccine Act's preponderant evidence standard that petitioners submit "objective confirmation," such as medical literature. Id. at 1279. The Federal Circuit explained that requiring medical literature "prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of the injured claimants." Id. at 1280 (citing Knudsen, 35 F.3d 543, 549 (Fed. Cir. 1994)); see also Capizzano v. Sec'y of Dept. of Health & Human Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006) [hereinafter "Capizzano III"]. Moreover, the Federal Circuit stated, "The purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." Id. Petitioners' case is measured against these standards.

Summary of Experts' Positions

The following is a brief overview of the experts' testimony.

Petitioners' Expert Dr. S. Gerald Sandler

Dr. Sandler is a Professor of Medicine and Pathology at Georgetown University Medical Center and director of Transfusion Medicine at Georgetown. Tr. at 14; see P Ex 19. He is a

[7] The undersigned reviewed the Federal Circuit's recent decision in Andreu, 569 F.3d 1367, to determine its potential impact on the outcome of this case. A status conference was held on July 10, 2009, to discuss whether the Federal Circuit's decision in Andreu could impact the outcome in this case and whether the parties wanted to file any supplemental briefing to reflect their positions on the issue. The parties agreed that Andreu did not alter the Federal Circuit's prior decisions on vaccine causation. The undersigned agrees. Thus, the parties declined the offer of filing supplemental briefs and requested a decision based on the current record.

member of the Division of Hematology, Oncology and the Lombardi Cancer Center and lectures on the subjects of hematology and transfusion medicine. Tr. at 15. He has also published on the issue of ITP. Id. at 16. However, Dr. Sandler's current clinical practice is "not extensive" and involves primarily adults. Id. at 71. Dr. Sandler was admitted as an expert on blood and blood diseases. Tr. at 18.

Dr. Sandler testified that ITP can be divided into three different categories. Specifically, he stated that the most common division of ITP is acute versus chronic. Id. at 22. Acute "meaning it comes on quickly, goes away quickly"; chronic "meaning [lasting] more than six months." Id. The second division of ITP is childhood versus adult ITP. Id. This division is important to this case because roughly 90% of children develop acute ITP, whereas adult ITP cases present just the opposite, almost all adult cases are chronic. Id. at 23. There are exceptions however, kids do present with chronic ITP and adults do present with acute ITP. Id. Dr. Sandler's contention in this case is that Katelyn presented as an exception to the general rule, that is kids generally present with acute ITP, and thus the general standards for evaluating causation, specifically the timing issue, do not apply. For completeness, Dr. Sandler testified to the third division of ITP, primary vs. secondary. Tr. at 23. Dr. Sandler defines secondary ITP as having a "causal relationship to something else," with primary ITP comprising the remainder of cases. Id. This third division is not critical to the discussion herein.

As stated, Dr. Sandler opined that Katelyn suffers from an uncommon form of ITP, that is part of the 5% of cases in children that go on to have the chronic form of ITP. Tr. at 23, 31. He stated that it is his "very strong opinion" that these five percent of cases, chronic form ITP in children, have a very different presentation than the 95% with acute ITP. Tr. at 31. Importantly, the presentation of ITP in these 5% of cases have an "insidious" onset. Id. at 28. Dr. Sandler explained that insidious in this sense means "below the surface." Id. He emphasized that "you don't have to have bruises to have ITP." Id. Thus, Dr. Sandler's opinion relies on an insidious presentation of ITP, occurring without noticeable bruising, to establish a temporal relationship to the vaccination. However, he acknowledged that the fact of insidious onset causes a difficulty for petitioners' case of causation, that is it is **difficult** to determine the specific date of onset of Katelyn's ITP. Tr. at 47 (emphasis added). However, Dr. Sandler maintained his position that the MMR vaccine was the likely cause of Katelyn's ITP on the basis of (1) the mother did not have ITP and thus, antibodies were not transferred from mother to baby, (2) at birth and prior to receipt of her MMR vaccination there was no evidence of thrombocytopenia, (3) Katelyn developed ITP less than 38-weeks after her MMR vaccination, and (4) on July 7, 2004 Katelyn was diagnosed with chronic ITP. Tr. at 57-62; P Ex 18 at 1-5 (petitioners' expert report).

Respondent's Expert Dr. James Nachman

Dr. Nachman is a pediatric hematologist/oncologist who is currently a Professor of Pediatrics at the medical school at the University of Chicago. Tr. at 101. He is board certified in pediatrics and pediatric hematology/oncology and his medical practice focuses on seeing children and young adults (approximately 200-250 in any given month). Tr. at 102. Dr. Nachman

estimated that he has diagnosed or treated 300-400 cases of ITP in children over his career. Id. at 103. Dr. Nachman was admitted as an expert in the field of pediatric hematology. Tr. at 103-05.

Dr. Nachman opined that Katelyn's medical records supported a diagnosis of acute ITP during her initial diagnosis in July 2003. Tr. at 111, 115. Dr. Nachman also agreed that one could say Katelyn had chronic ITP at one year given her platelet count, "but we wouldn't call her as having chronic ITP now by any stretch of the imagination because in our experience, especially if you've gone three years with a normal platelet count, the chance for a reoccurrence is very, very small." Tr. at 117. He opined that because a case of ITP persists beyond a year, and could be coined "chronic," onset is not necessarily insidious. Tr. at 120. Based on the medical records he opined that onset occurred within 6-9 months following immunization. Tr. at 137. He stated that he is not aware of any evidence in the medical literature or elsewhere linking MMR with ITP with an onset 26-38 weeks post-vaccination. Tr. at 121. It is his opinion that onset within 26-38 weeks does not constitute a medically appropriate time frame. Id. In conclusion, based on his academic experience and training, clinical experience, research and review of the medical literature and other materials in the case he does not believe that Katelyn's ITP was caused, in fact, by her vaccination. Tr. at 121-22.

Discussion

The primary issue to be decided is prong three of Althen, whether there is a showing of a proximate temporal relationship between Katelyn's MMR vaccination and Katelyn's injury. Althen, 418 F.3d at 1278; DeBazan v. Sec'y of HHS, 539 F.3d 1347, 1352 (Fed. Cir. 2008) ("proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." (citing Pafford v. Sec'y of HHS, 451 F.3d 1352, 1358 (Fed. Cir. 2006))); P Post-Hearing Brief at 1. There is no dispute that Katelyn had ITP. See Tr. at 11, 125. There is no dispute that the MMR vaccine can cause ITP. See id. at 110. There is also no dispute that the medically appropriate timeframe for an acute presentation following immunization is approximately six weeks. Id. at 90-92, 110; see also P Exs 31-35. It is also accepted that the medical records do not record signs of ITP until more than six months following vaccination, which is far beyond the medically accepted timeframe. Tr. at 72, 73, 76, 121; see also Fact Ruling at 2. Based upon Dr. Sandler's testimony, the dispute in this case centers on whether Katelyn's ITP presented unusually, that is a chronic form of ITP, and thus the accepted medical timeframes do not apply. See P Ex 37 at 1 ("The unresolved issue is the uncommon case of chronic ITP."). On this point the undersigned finds that petitioners failed to make their case.

First, a comment on the expert testimony is necessary. While both experts were highly qualified, the undersigned found Dr. Nachman's testimony far superior and vastly more persuasive. Given Dr. Sandler's credentials, the undersigned was, quite frankly, surprised at the superficiality of his testimony. The Federal Circuit has repeatedly made clear that petitioners' theory of causation must be supported by a "reputable medical or scientific explanation."

Andreu, 569 F.3d. 1367, 1379-80 (citing Althen, 418 F.3d at 1278.). The assessment of the reliability of petitioners' explanation can involve "assessment of the relevant scientific data," evaluated however through the prism of the Vaccine Act's preponderance standard. Id. at 1380. The undersigned finds that Dr. Sandler's testimony was unpersuasive and failed the test of reliability. On the other hand, Dr. Nachman's testimony cogently explained why Katelyn's case was not "atypical" and thus the onset of Katelyn's ITP was far removed from the medically acceptable timeframe for onset. This case devolved to a battle of the experts. In resolving the issue, the undersigned finds that Dr. Nachman was more persuasive. Thus, after a complete review of the record, the undersigned finds that Dr. Nachman's opinion that the vaccine played no causative role in this case prevails.

The essence of Dr. Nachman's testimony and opinion in this case is as follows:

> [B]ased on the medical record, this is an acute onset ITP because in 4/15 we have a child who is perfectly healthy and had no history of anything taken by a nurse practitioner who then develops the sudden onset of a huge knot on her side, which is clearly an abnormal finding - bruising on the lower extremities can be cause by anything but not a big knot on the side - she has an abnormal platelet count, a year later her platelet count is up to 89,000, within the next five months her platelet count is perfectly normal and her platelet count has remained perfectly normal for the last three plus years. So in pediatrics we wouldn't even consider her as having chronic ITP because it has no meaning. She's fine, she doesn't require any intervention, et cetera.

Tr. at 107-08; see also id. at 117. Dr. Nachman did concede later that Katelyn would be considered to have had chronic ITP to the extent that at one year her platelet count was slightly elevated, "but we wouldn't call her as having chronic ITP now by any stretch of the imagination." Id. at 117.[8]

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[8] Petitioners criticized Dr. Nachman for presenting "inconsistent" testimony regarding the definition of chronic ITP. P Post-Hearing Brief at 7. The undersigned does not agree. Katelyn's ITP was initially diagnosed by her treating doctors as acute ITP. P Ex 4 at 20 ("probably acute ITP"); Id. at 45 ("newly discovered ITP"); P Ex 37 at 1(Dr. Sandler notes the diagnosis of acute ITP was updated on April 7, 2004 to chronic ITP). The diagnosis was later changed to chronic with its persistence. P Ex 4 at 76. Contrary to petitioners' contention, the definition of chronic is not set in stone. Petitioners' literature is actually more consistent with Dr. Nachman. P Ex 39 at 6-7 ("A recent study showed that 26% of children with persistent thrombocytopenia recovered from ITP between 7 and 12 months after diagnosis. This suggests that the current definitions of chronic ITP may not be appropriate."); P Ex 40 at 3 ("Cut off point of six months does not accurately define chronic ITP, as significant proportion of children resolve later in the course of the disease."). As Dr. Nachman explained:

> The fact that Katelyn recovered her platelet count between 6 months or 1 year in no way implies that the mechanism of her platelet count was different than that for a patient who

Dr. Nachman provided a detailed explanation of the biological mechanism of ITP. Many cases of ITP involve the body mounting an immune response in the form of antibodies. Tr. at 118; Tr. at 109 (almost all cases of ITP in children are immune-mediated); see also R Post-Hearing Brief at 14-15. This occurs due to the body producing antibodies to a virus. Tr. at 119. The body does not actually make antibodies to its own platelets. Tr. at 119.[9] Instead, the antibody made in response to the virus, "recognizes something on the surface of the platelet" and as the antibody titer increases the antibody coats the platelet. Id. This is because "[s]omething on the surface of the virus looks like something on the surface of the platelet." Id. Once the platelet is coated with antibody "the spleen recognizes that they are coated and yanks them out of circulation." Id. Generally, the antibody response peaks within two to three weeks after exposure. Id. The body reaches a threshold and "then all of the sudden the platelets start to crash," which is "why we see this acute onset." Tr. at 119. While platelet counts may be falling prior to the crash, it is "generally a pretty explosive phenomenon in pediatrics." Tr. at 120. The medical treatment utilized is not designed to treat the cause of ITP. Tr. at 119. Alternatively, steps are taken to slow the spleen down in taking the antibody coated platelets out of circulation. Tr. at 119. Over time "the antibody titer goes down and the ITP goes away in the vast majority of cases." Id. The most common association seen with "childhood ITP is the 'viral syndrome,' with no reference to a particular virus." Tr. at 108. Dr. Nachman categorizes viral syndromes as an unknown cause if further details regarding what virus was involved are not known. Tr. at 109. Therefore, he states the majority of cases in pediatrics have an unknown cause. Id. In cases of ITP with a known viral exposure onset generally occurs within 3-4 weeks and is "fairly explosive." Tr. at 108-09. MMR is sometimes associated with children with onset presenting within 30-40 days after vaccination. Tr. at 110.

In this case, Dr,. Nachman clearly stated that Katelyn's case was not atypical from what he sees in his referral practice. Tr. at 111 ("Katelyn's course is not particularly atypical"); Tr. at 112 ("[T]his is not an atypical case"); Tr. at 113 ("So this is not that atypical for what I see in my referral practice all the time."). In sum, this is a child with an "acute ITP that took a little bit longer than we usually see to resolve." Tr. at 117. Most children cases go away "within a year's timeframe, and a very, very, few, if any, have long-term chronic ITP," with decreased platelets for periods of multiple years duration. Tr. at 107. Dr. Nachman opined that "we wouldn't even

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> recovered their platelet count less than six months from onset. The relevant endpoint is whether or not the patient attains a normal platelet count and maintains it rather than the time at which the normal platelet count was observed.

R Ex C at 1.

[9]Petitioners submitted literature supporting that ITP can be divided into a childhood and adult form. P Ex 41 at 6. Interestingly, the literature appeared to indicate that the mechanism of ITP was distinctly different in the acute childhood form versus the chronic adult form. Id. "The forms may be pathophysiologically distinct; the acute childhood form characterized by platelet coating with immune complexes and the chronic adult form by the presence of specific platelet antibodies" Id. This difference was not probed in depth at the Hearing.

consider her to have chronic ITP because it has no meaning." Tr. at 108. This is because Katelyn's platelet count returned to normal and she does not require any intervention. Tr. at 108. Katelyn had chronic ITP "only to the extent that at one year her platelet count was slightly normal[10] but we wouldn't call her as having chronic ITP now by any stretch of the imagination because in our experience, especially if you've gone three years with a normal platelet count, the chance for any reoccurrence is very, very small." Tr. at 117. Further, just because a case of ITP persists for more than a year does not necessarily mean that onset was insidious. Tr. at 120. Dr. Nachman stated firmly that there is "no reason to suggest anywhere that there's an insidious onset here." Tr. at 112.

As noted above, it is not contested that the medically appropriate timeframe for the onset of symptoms post-immunization for acute ITP is approximately six weeks. See P Ex 30 at 1-2 ("increased risk of ITP with onset 15-35 days after immunisation," "risk period 0-42 days,"); P Ex 31 at 1 (increased risk of ITP within 6 weeks after MMR vaccination, "however, the attributable risk of ITP within 6 weeks after MMR vaccination is low."); P Ex 32 at 3 (clinical picture of acute ITP after vaccination similar to natural infections, i.e., with rubella, TP typically presents within a few days after rash which occurs 18-24 days after contact); P Ex 33 at 2 (4 vaccine related cases of ITP occurred with onset at 19, 21, 22 and 34 days post-vaccination); Tr. at 92 (citing to P Ex 34 (article in French) petitioners' expert agrees with respondent's statement that "it seems authors conclude that onset of ITP within 10 to 22 days after MMR is likely to be vaccine related"); P Ex 35 at 3-4 (60 cases of TP in children ages 1-11 years occurred 2-45 days after vaccination of 1 of 7 vaccines, "[a]ll TP episodes occurred 2 to 45 days after immunization"); Tr. at 71 (Dr. Sandler agreed that a time frame termed as "recent" is generally within a couple weeks to as late as four to eight weeks). The highest incidences within the six week time frame are demonstrated to occur within roughly two to four weeks post-vaccination. P Ex 30 at 2 ("highest relative incidence in the six weeks after MMR was found between 15 and 28 days"); P Ex 31 at 4 (7 of the 8 cases of ITP attributed to the vaccine occurred between week 2 and week 4 post-vaccination). In fact, according to one of the articles submitted by petitioners the estimated relative risk "during the period from 7 to 26 weeks after MMR vaccination was not significantly elevated." P Ex 31 at 4. The literature reports and the experts do not dispute that the literature supports an onset of ITP within 6 weeks post-vaccination as attributable to MMR. See Tr. at 91-93 (Dr. Sandler agrees that the maximum timeframe that the authors attribute a causal relationship of ITP to MMR is onset within six weeks post-vaccination).[11]

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[10]Transcript reads "normal," but in context the undersigned believes the transcript should read "abnormal."

[11] Dr. Sandler wrote in his report that one article supported a timeframe of 49 weeks. P Ex 18 at 5. The article petitioners' expert cites in his expert report states that cases of ITP "have been reported in the peer-reviewed medical literature as late as 49 weeks following MMR immunization." P Ex 18 at 5 (citing to an article by Elizabeth Miller, et al., for the proposition of onset reported as late as 49 weeks, P Ex 30 at 2, figure 1). This article was discussed in depth during the Hearing. See Tr. at 84-89. Ultimately, Dr. Sandler agreed with respondent's interpretation of the article that "[t]his figure isn't making any statement about whether ITP was causally related to MMR, is it?" Tr. at 85. Without

In this case, Katelyn did not present with symptoms of ITP post-vaccination within six weeks. In fact, her symptoms are documented in the medical records much later. Katelyn received her immunizations on October 15, 2002. As detailed in the Fact Ruling, Katelyn was seen for a physical exam on April 15, 2003. This is six months after her immunizations. Noticeably, there is no mention of bruising by the nurse who viewed the child, nor any concerns raised by the mother. Affidavit of Donna Jackson; P Ex 4 at 18. It was not until mom reported bruising on July 9, 2003, occurring "over the last several months" that the medical records record the symptoms of ITP and ITP was diagnosed. P Ex 3 at 18. Based upon these records, the undersigned found that "the bruising seen on Katelyn was nothing out of the ordinary for her until sometime after the April 2003 visit and prior to the July visit." Fact Ruling at 2. Dr. Sandler did not take issue with any of the information contained in the medical records. Tr. at 72 ("I don't dispute anything in the medical records that I recall."). Thus, based upon the medical records and the Fact Ruling, the onset of Katelyn's acute ITP was anywhere between six and nine months. In fact, the parties agreed that symptoms of Katelyn's ITP presented sometime after Katelyn's April 15 visit and prior to her July 8 visit, roughly a time frame of 6-9 months post-vaccination. Tr. at 78 (Dr. Sandler agrees "[t]here was nothing recorded," for at least six months post-vaccination and regarding her history "whatever the doctors wrote I would accept"). This is a medically inappropriate timeframe for causation. See Tr. at 121; see also P Exs 31-35. Accordingly, petitioners' case fails the third part of the Althen test, establishing an appropriate temporal relationship between the vaccination and injury, and thus this Petition must be dismissed. Althen, 418 F.3d at 1278; see also DeBazan; 539 F.3d at 1352.

In making this finding, the undersigned rejects Dr. Sandler's testimony. In short, Dr. Sandler's testimony was found to be unpersuasive. It was not "sound and reliable," Knudsen, 35 F.3d at 548, but was at times extremely confusing, internally inconsistent, and appeared to the undersigned to be result oriented. Despite his impressive credentials, the undersigned was not impressed with the quality of Dr. Sandler's testimony. Dr. Sandler's theory of causation and testimony is addressed in some detail below.

Petitioners recognize that this case devolves to a classic battle of the experts and thus describes Dr. Sandler as a "foremost" expert on blood diseases, P Post-Hearing Brief at 4, a "foremost" expert on ITP, id. at 12, and a "renowned" expert on ITP. Id. at 14. In contrast, petitioners attempted to denigrate Dr. Nachman's testimony. Id. at 7. Both experts are highly qualified to testify on the issues of ITP. While Dr. Sandler undoubtedly possesses a stellar CV, P Ex 19, there is no basis in this record to say that he is a "foremost" or "renowned" expert. That would require a comparison to colleagues in the field, a comparison that we do not have. It is important to note however that Dr. Sandler does not have an "extensive" clinical practice presently and what practice he does have is primarily with adults. Tr. at 71. He is also not a pediatric hematologist and obviously not board certified as such. Id. Dr. Nachman on the other hand is a board certified hematologist and has treated children with ITP. Tr. at 102-03. In fact,

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causally linking the reported incidences of ITP to the MMR vaccine this article does not provide support for petitioners' case.

he sees about ten new cases per year and between 300 to 400 of pediatric ITP cases over his career. Id. at 103. Thus, in discussing the "hands on" issues of what acute and chronic ITP looks like, how it manifests and how it progresses in children, Dr. Nachman is certainly in a better position to opine than Dr. Sandler. In addition, having viewed the witnesses and considered the substance of their testimony, the undersigned is convinced beyond any doubt that Dr. Nachman, not Dr. Sandler, was the far more persuasive witness. Hanlon v. Sec'y of HHS, 191 F.3d 1344, 1349 (Fed. Cir. 1999) (special master made credibility determination based on expert's reputation and quality of testimony, which the court stated "such credibility determinations are 'virtually unreviewable'")(citing Bradley v. Sec'y of HHS, 991 F.2d 1570, 1575 (Fed. Cir. 1993))).

Petitioners' theory of this case, in a nutshell, is that Katelyn's ITP is an exception to the general rule that children manifest ITP acutely; Katelyn manifested chronically. As Dr. Sandler stated several times, "chronic is a different disease from acute." Tr. at 54. Dr. Sandler continues that chronic ITP manifestations are "insidious," meaning that it is below the surface without visual bruising. See Tr. at 28. The sum and substance of this argument is that the accepted timeframe of six weeks for acute presentation of acute ITP does not apply and the fact that bruising was not seen until six to nine months following vaccination is not a hurdle to causation. However, there are numerous problems with Dr. Sandler's testimony.

First and foremost, Dr. Nachman adamantly and persuasively testified that Katelyn's case is not "in any way particularly atypical for what I see in my practice." Tr. at 135. He stated, contrary to Dr. Sandler, that this is an acute onset case, id. at 107, allowing that it was chronic "only to the extent that" it lasted one year, id. at 117, there is "no reason to suggest anywhere that there's an insidious onset here," and that merely because a case persists beyond one year does not mean that the onset of the ITP was insidious. Id. at 120; see also R Ex C at 1. Katelyn's treating doctor's diagnosed her ITP as acute, changing the diagnosis to chronic due to its persistence. P Ex 4 at 20 ("probably acute ITP"); Id. at 45 ("newly discovered ITP"); P Ex 37 at 1 (Dr. Sandler notes the diagnosis of acute ITP was updated on April 7, 2004 to chronic ITP). Again, based upon Dr. Nachman's background and experience with treating pediatric ITP patients and his testimony in this case, his testimony is accepted over that of Dr. Sandler's.

But also very importantly to the undersigned's resolution of this case, Dr. Sandler's testimony failed the touchstone test of reliability. The key to his theory was that the five to ten percent of children that have the chronic form of ITP will present with a different clinical picture, that is with an insidious onset. See Tr. at 31. While Dr. Nachman appeared to recognize "very, very rare" cases where ITP presents with no manifestations of bruising, tr. at 115, and indeed the medical literature supports the insidious onset, see P Exs 38-42, what was never established was **the equating of chronic with insidious onset.** The premise for Dr. Sandler's testimony was the notion that Katelyn's ITP was chronic and thus the onset was insidious. See P Post-Hearing Brief at 1-2. If this was true, the lack of perceptible bruising and possibly the extended timeframe following immunization may be explained. However, Dr. Sandler never made the case, despite several rounds of questioning by the undersigned, that chronic ITP presents in all

instances insidiously. This is critical because without the insidious onset petitioners have no explanation for the lack of bruising, the extended timeframe following immunization and the lack of support in the medical records. Dr. Nachman unquestionably disagreed with the proposition. Tr. at 120. In fact, as will be discussed, petitioners' literature shows the opposite.

First, the undersigned questioned Dr. Sandler on several occasions what is the support for the proposition that if you have chronic ITP then it follows that the manifestation was insidious. See Tr. at 28-29. Dr. Sandler never satisfactorily answered that question. Dr. Sandler's first effort to equate chronic ITP, which can occur in five percent of children,[12] with insidious onset utilized petitioners' Ex 36, a three page fact sheet on ITP from an NIH website. See Tr. at 19-28. Through questioning it became clear that Dr. Sandler was relying on one line in the fact sheet to equate chronic ITP with an insidious onset. Tr. at 28. Dr. Sandler highlighted the line which stated "[p]eople who have ITP often have purple bruises" and noted that "you don't have to have purpura all the time to have ITP." Id.; P Ex 36. While Dr. Sandler opined that "the word chronic insidious implies that it's below the surface, it percolates without being on the surface," tr. at 30, he agreed with the undersigned that the article he relied upon for five percent of the children presenting chronically does not support the proposition that chronic means insidious. Id. at 31 ("Yes, I agree with you." (referencing an article from the National Heart, Lung and Blood Institute of HHS. P Ex 36.))[13] Dr. Sandler maintained however that:

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[12]One additional interesting factor taken from petitioners' literature, the rarity of chronic ITP in children is subject to question. Dr. Sandler began his testimony by stating that "something around five to 10 percent" of children get chronic ITP. Tr. at 23. Dr. Sandler never stated where he got those figures from, however, he did agree to counsel's reference to a five percent figure in the two page internet fact sheet from the NIH. Tr. at 25-26. This became the basis for what petitioners characterizes as a "rare" case of ITP, tr. at 27; P Post-Hearing Brief at 5 ("extremely unusual"), and Dr. Sandler testifying that Katelyn is "in the five percent of 100 percent of children." Tr. at 27; see also id. at 54. However, petitioners' literature raises some questions regarding the percentage of children that have chronic ITP. In petitioners' Ex 41, a study of childhood ITP, it states that the "overall proportion of chronic ITP (25.1%) found in our study is within the range described in previous large investigations." P Ex 41 at 6. And in petitioners' Ex 42 the percentage of chronic cases of ITP in children is "approximately 10-20%." P Ex 42. Thus, the percentages of children with chronic ITP far exceed the five percent figure relied upon by Dr. Sandler for his theory of causation and in none of the literature submitted by petitioners does it indicate that children with chronic ITP is "rare" or "unusual."

[13] Petitioners refer to petitioners' Ex 36 to support this proposition of drawing a distinction in presentation of acute versus chronic ITP in children. Tr. at 48 (citing P Ex 36). The undersigned made it quite clear that review of the article does not provide the support petitioners are seeking. Tr. at 48. ("I think you are reading far too much into this two page thing. In fact, the five percent is under acute ITP, it's not under chronic ITP...[ ] I don't think we can interpret and extrapolate from that piece what you want out of it."). Id. The undersigned describes the article as saying "you have an acute onset and then in five percent of the cases it doesn't go away." Tr. at 50-51 (referring to P Ex 36 at 2)**. Petitioners acknowledged that the article does not say anything specifically about an insidious onset.** Tr. at 51 (emphasis added).

> my very strong opinion [is] that the five percent is the five percent of these cases have a different clinical presentation than the 95 percent.

Tr. at 31. The undersigned impressed upon Dr. Sandler that that is the issue that must be established. Id.; see also id. at 51. However, Dr. Sandler continuously turned to the five percent figure as "outside the general" or typical case, tr. at 32, and essentially equating those cases with insidious onset. See Tr. at 33-34.

When pressed for some support for his testimony that chronic ITP is insidious, tr. at 45, Dr. Sandler forthrightly stated that the data is limited and extremely hard to come by. Id. at 49 ("detailed information in children who are two years old . . . [is] exceedingly difficult to get that kind of information."). Dr. Sandler offered to provide a "good analogy to explain how biology works to explain it." Tr. at 35. Thus, Dr. Sandler relied upon his experience with insidious onsets in adults and an analogy to the HIV virus to support his testimony. As the Federal Circuit has taught us, petitioners need not produce medical literature to support their claim. Andreu, 569 F.3d at 1379 ("requiring 'objective confirmation' in the medical literature prevents 'the use of circumstantial evidence ...and negates the system created by Congress' through the Vaccine Act.") (citing Althen, 418 F.3d at 1280))). However, petitioners must produce some indicia of reliability for their theory of causation. Andreu at 1379-80. If Dr. Sandler's testimony regarding the analogy to the HIV virus and his adult experience was persuasive, such testimony may meet the Federal Circuit's test of reliability. However, Dr. Sandler's testimony fell woefully short.

Describing how an insidious onset would manifest in an adult, Dr. Sandler stated that an adult may present initially with bleeding gums. Tr. at 29. After finding a low platelet count, a further history may reveal for example the patient saying, "[w]ell you know, last summer when I played baseball I bruised all over the place, and I mean, I've never done that before...you know, the dentist told me a year ago that when I was in there that I was bleeding more than normally but I never did anything about it." Tr. at 29. Dr. Sandler explained that the onset is insidious because you cannot pinpoint exactly when the ITP started, however, looking retrospectively at the historical events symptoms of ITP are recognized that previously were not considered. Id. Katelyn's factual picture does not comport with Dr. Sandler's explanation of an insidious onset.

As stated above, based upon the medical records, the parties agreed that symptoms of Katelyn's ITP presented sometime after Katelyn's April 15 visit and prior to her July 8 visit, roughly a time frame of 6-9 months post-vaccination. Tr. at 78 (Dr. Sandler agrees "[t]here was nothing recorded," for at least six months post-vaccination and regarding her history "whatever the doctors wrote I would accept"). There is no evidence, and Dr. Sandler did not point to any, of bruising or bleeding that viewed retrospectively could be seen as symptoms of ITP. Thus, unlike the examples Dr. Sandler gave for adult chronic ITP, Katelyn's factual picture is not analogous. Accordingly, Dr. Sandler's explanation is not persuasive.

There are however indications in the medical records that Katelyn had bruised prior to immunization. Fact Ruling at 1. Katelyn's mom reported during the July 8, 2003 office visit

that Katelyn "has always bruised easily," and the number of bruises has increased since she started walking. P Ex 3 at 18 (Katelyn is described by her mother as "very active" and "very accident prone."). Dr. Sandler did not rely upon these notations of earlier bruising as part of what was ultimately diagnosed as ITP because "the mother impressed me through the medical records as a loving, caring person who was not a particularly astute clinical observer. I would put her in the category of someone whose history I would have a hard time interpreting." Tr. at 60-61. This creates quite a dilemma for petitioners. On the one hand, if mom's history was accepted, the retrospective bruising that Dr. Sandler discussed in relation to the adult chronic ITP would be substantiated, giving much needed credence to his testimony. However, again if accepted, this would create another issue for petitioners - the onset of the ITP would have pre-dated the immunizations.[14] As Dr. Nachman commented "you can't have it both ways." Tr. at 132. Dr. Sandler recognized the problem, that is "[w]e don't have a history." Id. at 61. But the answer is not to manufacture or assume facts for purposes of proving a theory. The history that we do have to work with is in the medical records. And that history, which Dr. Sandler has not taken issue with, is that the evidence of Katelyn's ITP began six to nine months following immunization and there is no indication in the medical records of an insidious onset consistent with the examples given by Dr. Sandler from his experience with adult cases.

The undersigned was also unconvinced of the applicability of the HIV Model as support for petitioners' medical theory. Dr. Sandler analogizes his theory of Katelyn suffering an "insidious" onset of ITP to the HIV model of infection. Tr. at 63, 38, 42. He discusses HIV because it is a virus and "it has an insidious character" to it. Tr. at 63. Dr. Sandler also finds it pertinent because "HIV/AIDS does cause acute immune thrombocytopenic purpura secondary to the infection..." Tr. at 63. Essentially, he says that HIV infection can have a delayed immune-response, often times with years elapsing before full-blown AIDS develops. Tr. at 63. He discusses how "[l]ow platelets, immune thrombocytopenia, is part of that." Tr. at 64. Dr. Sandler's opinion is that this is a "very good example of how a virus can be exposed to the immune system and have an insidious course coming up quite a bit later." Tr. at 64. Dr. Nachman disagrees with the applicability of the HIV model in this case. Tr. at 120. The reason for this is because of the specific mechanism of how HIV affects the body as an ongoing virus that builds up and paralyzes the immune system itself. Tr. at 120. In contrast, the MMR vaccine is "a live, attenuated virus which doesn't seem to persist." Tr. at 120.

Dr. Nachman describes that in ITP the function of the immune system itself is not compromised, and is "perfectly normal." Tr. at 124. In contrast, HIV is an ongoing, active infection. Id. HIV virus "actually destroys certain cells of the immune system" by attaching to certain cells of the immune system and killing them. Tr. at 122. As the viral load increases the cells in the immune system decrease and a person becomes immune paralyzed. Tr. at 122. When HIV is treated and the viral load decreases, "many of the manifestations go away." Tr. at 123. While Dr. Nachman agreed HIV can cause thrombocytopenia, under such circumstances

[14]The undersigned raised this scenario in the Fact Ruling, indicating that a theory of significant aggravation might be the avenue of causation. Petitioners rejected that theory of causation. Tr. at 7.

thrombocytopenia presents as a completely different phenomenon because of the "immune disregulation that occurs" in HIV infected persons. Tr. at 124-23. Dr. Nachman testified that "[t]hrombocytopenia often goes away" when HIV patients are treated with antiretroviral drugs. Tr. at 123. In conclusion Dr. Nachman opines that "[i]n ITP, the immune system is perfectly normal. In HIV, the immune system is paralyzed and destroyed almost by this virus." Tr. at 124. Thus, Dr. Nachman concludes:

> This is a whole different scenario. This has nothing to do with HIV. HIV is an ongoing, active infection that kills immune cells. The immune system in ITP is perfectly normal. You can't draw any analogy from HIV to ITP.

Id. While the HIV model may describe an insidious onset, the unrebutted testimony of Dr. Nachman shows clearly that the HIV model is not analogous to the ITP pathological process and thus does not support petitioners' theory that Katelyn was suffering from an insidious onset.

Katelyn's medical course neither comports with Dr. Sandler's adult model, nor with petitioners' medical literature. While the literature does indicate that chronic ITP typically presents insidiously, the articles do not support that all chronic ITP cases present insidiously. See P Exs 24, 27, 41. However, even more importantly for purposes of this case, when chronic ITP presents insidiously, contrary to Dr. Sandler's testimony, the ITP will manifest prior to the obvious bruising. As discussed below, this prior manifestation is born out by Dr. Sandler's own adult analogy, Dr. Sandler's expert report and petitioners' literature.

As discussed at page 14, supra, Dr. Sandler's adult model of chronic ITP revealed signs of unusual bleeding that the individual did not recognize as a medical problem but when viewed retrospectively by the medical professional are determined to be symptoms of the chronic ITP. Dr. Sandler's report discussing Katelyn's alleged ITP appears to recognize that signs of the ITP should appear prior to the obvious symptoms. See P Ex 18 at 5. However, since there is no evidence of any bruising prior to Katelyn's diagnosis, Dr. Sandler resorts to conjecture in his report stating:

> While Mrs. Doyle appears to be a loving and caring mother, I do not find her to be characterized in the medical records as an astute, clinically precise observer. In my opinion Mrs. Doyle's **failure to report a few pinpoint-size petechiae** on her child's legs prior to the appearance of gross bruises (and a medical diagnosis of chronic ITP) is more likely a function of her low threshold for observation than it is that they were not there reflecting an earlier onset of thrombocytopenia.

Id. (emphasis added). This is contrary to Dr. Sandler's testimony that you do not need bruising to diagnose ITP. Tr. at 28, 33. Petitioners' medical literature also supports the appearance of mild bruising prior to the obvious bruising. See P Ex 41 at 7 (The authors describe the insidious onset as "one with slow onset of milder symptoms."); see also P Post-Hearing Brief at 8 ("[C]hronic ITP tends to have an insidious and mild onset.").

In this case it was conceded, and the medical records support, that Katelyn exhibited no bruising or other signs of mild bleeding following immunization until between six and nine months following immunization. Dr. Sandler agreed that there was "nothing recorded" in the medical records indicating ITP for at least six months post-vaccination. Tr. at 78. In fact, Dr. Sandler clearly stated that he has "no quarrel with the medical record." Tr. at 72. Dr. Nachman stated regarding the possibility of any bruising prior to the obvious signs discovered at the July 8, 2003 visit that a medical professional would have found any signs of bruises or petechiae. Tr. at 116; see P Ex 18 at 3. Katelyn was examined by nurse Donna Jackson on April 15, 2003 and no bruising was seen. Fact Ruling at 2; P Ex 3 at 16. Contrary to petitioners' assertion that the Katelyn's "medical record illustrates a mild and insidious onset," P Post-Hearing Brief at 8, there is no evidence of any bruising on Katelyn following her immunizations until her doctor's visit on July 8, 2003. P Ex 3 at 18.

Dr. Sandler's theory of causation is based upon an acceptance that chronic ITP in children manifests insidiously that has not been established. In fact, under Assessment/Diagnosis/Plan, in the notes from her hospital visit, the doctor wrote that Katelyn's condition was "probably acute ITP." P Ex 4 at 20. Dr. Nachman, who has treated 300-400 cases of pediatric ITP, testified convincingly that this is a case of acute ITP. Tr. at 107-08, 117. Katelyn's presentation does not comport with Dr. Sandler's models of how chronic ITP would manifest, that is with some prior signs of bleeding. Tr. at 112, 115-16. Dr. Sandler's models are consistent with medical literature submitted by petitioners. The medical records do not record any signs of bleeding subsequent to immunization until nine months after. Dr. Sandler does not take issue with the medical records and agrees that nine months is outside the timeframe for a temporal relationship. Petitioners' case fails to meet their expert's model, the medical literature and the medical records. The undersigned cannot conceive of a less reliable, more unsound medical opinion. Andreu, 569 F.3d 1367.

The undersigned addresses briefly one last point of Dr. Sandler's testimony on the temporal relationship that never made sense to the undersigned. That is, what was the evidence of the starting point of the process? With this insidious onset, Dr. Sandler stated that it is "difficult to say when this started." Tr. at 47; see also P Post-Hearing Brief at 8 ("determination of the precise date of onset medically impossible"). In addition, with the insidious onset, you do not have to have bruising. Tr. at 28, 33,34. Because of this insidious onset, Dr. Sandler stated that he could not "extrapolate" back from Katelyn's extensive bruising. Id. at 37. Thus, if you cannot determine when the onset of the ITP was because of the insidious onset, how can one reasonable state that the onset was after the immunization? Why is it not possible that the ITP began prior to the immunization?

The undersigned questioned Dr. Sandler on why he was fingering the vaccination as the cause of Katelyn's ITP when he was testifying to an insidious onset that we don't know when it began. Tr. at 61. The undersigned expressed this concern during the Hearing, "if the doctor is saying we don't know the history or we don't know the onset of this thing, **how do we know if it**

started after vaccination? It could have started at any point." Tr. at 47 (emphasis added). Dr. Sandler stated at various points in the Hearing that "[w]e don't have a history", tr. at 61, and that "[i]t was difficult to say when this started." Id. at 47. Dr. Sandler was also asked by counsel that given the finding of ITP nine months following vaccination could he based upon the information in the medical record "extrapolate backwards" and opine whether Katelyn's platelet count was reduced within 30 days of the vaccine. Dr. Sandler replied, "I cannot extrapolate back. I cannot prove that position." Id. at 37. Counsel asked again, "[w]hy can't you say when she got [the ITP]?" Tr. at 57. Dr. Sandler noted that the non-verbal nature of a two year old leaves you "with a lack of information on which you could be secure." Id. However, there was significant information from at least two adults. Katelyn's mother reported no recent bruising during the April 15, 2003 office visit. P Ex 3 at 16-17. After a thorough exam during the April 15 visit Nurse Jackson observed no abnormalities. P Ex 3 at 16. During the July 8, 2003 office visit Katelyn's mother reported that Katelyn "[h]as always bruised easily," and she was "more concerned now" due to a "very tender" "purplish" bruise on Katelyn's side. P Ex 3 at 18. Based on this information, the undersigned found "the bruising seen on Katelyn was nothing out of the ordinary for her until sometime after the April 2003 visit and prior to the July visit." Fact Ruling at 2. Despite this information, Dr. Sandler still opined that Katelyn's ITP developed after her MMR vaccination. Id. at 36. Dr. Sandler's testimony on this point simply was unpersuasive.

Respondent's counsel tried to clarify the point, asking "[w]ere you saying that with the insidious onset it was actually earlier than April or do you know?" Tr. at 76. Dr. Sandler stated that since some kids get ITP and some don't, "[o]nset in my mind was conception." Tr. at 77. He elaborated that the "onset of this problem is her genetic background." Tr. at 77. Dr. Sandler continued by stating that the "specific exposure was when she got measles vaccine and the onset of the process, which is under the surface, was as soon as that dose was absorbed by her body." Tr. at 77. Once again, Dr. Sandler's testimony tells us little and explains nothing. In stating that the vaccine was the triggering event to the underlying genetic makeup, Dr. Sandler fails to give even a hint to what medical fact points to the vaccine. This is especially critical given that, as stated above, Dr. Sandler stated repeatedly that we have no history to rely upon. What Dr. Sandler is remiss in recognizing or acknowledging is that we do have a history, as presented in the medical records, the onset of the ITP began six to nine months after immunization. This is far beyond a medically acceptable time for causation.

Dr. Sandler's opinion amounts to one assumption built upon another. He assumes that Katelyn has a chronic form of ITP that presents insidiously. We know from Dr. Nachman and the petitioners' literature that not all chronic ITP presents insidiously. Dr. Sandler assumes that Katelyn's ITP began post-immunization despite his concession that we have no reliable historical data to rely upon. He assumes that the mother failed to spot "pinpoint-size petechiae" prior to the gross bruises, P Ex 18 at 5 (Despite testifying that he agrees that there was no bruising seen by the nurse on April 15, 2003. Tr. at 76.). He maintains that this is a chronic ITP presenting insidiously despite the absence of any evidence of minor bruising prior to the diagnosis of ITP despite the literature and Dr. Sandler's testimony regarding his adult model stating that indicators of ITP will manifest prior to the obvious signs. Then finally, Dr. Sandler assumes a temporal

relationship between vaccine and injury of 38 weeks despite admittedly not knowing when the onset occurred.

Dr. Sandler is alone in believing the vaccine caused Katelyn's ITP. No treating doctor has indicated that the vaccine is causative. Dr. Sandler speculated that "[t]hey didn't even think of it." Tr. at 98. Or it is possible that the treating doctors not seeing any prior bruising and having a history of immunization six to nine months prior saw the case much like Dr. Nachman, there is no temporal relationship and thus no causation? In any event, the treating doctors' records are deserving of great weight. Capizzano, 440 F.3d at 1325. The totality of Dr. Sandler's opinion amounts to nothing more than "*post hoc ergo propter hoc*" line of reasoning. See Fricano v. Sec'y of HHS, 22 Cl. Ct. 796, 800 (1991). Unfortunately for petitioners the fact that ITP occurs sometime after a child is vaccination with MMR is not enough to prove causation. Hasler v. U.S., 718 F.2fd 202, 205 (6th Cir. 1993) (The vaccination is not the cause of every event that occurs after it.), cert. denied, 469 U.S. 817 (1994).

The undersigned finds no convincing evidence to support a finding of onset of ITP within the accepted post-vaccination time frame where ITP is associated with MMR vaccination. The undersigned finds petitioners failed to establish a proximate temporal relationship of Katelyn's ITP to the MMR vaccination given on October 15, 2002. Althen, 418 F.3d at 1278. Accordingly, the undersigned finds that petitioners have not established by a preponderance of the evidence that the MMR vaccination Katelyn Doyle received on October 15, 2002 was the legal cause of her ITP. Petitioners' claim is denied. The Clerk shall enter judgment accordingly.

IT IS SO ORDERED.

s/ Gary J. Golkiewicz
Gary J. Golkiewicz
Chief Special Master